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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,600	01/05/2004	Manfred Schudok	DEAV2003/0001 US NP	3011
5487	7590	08/01/2005	EXAMINER	
ROSS J. OEHLER AVENTIS PHARMACEUTICALS INC. ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			PAVIGLIANITI, ANTHONY JOSEPH	
		ART UNIT		PAPER NUMBER
		1626		
DATE MAILED: 08/01/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/751,600	SCHUDOK ET AL.
	Examiner	Art Unit
	Anthony J. Pavigliani	1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 05 January 2004.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1 - 11 is/are pending in the application.  
 4a) Of the above claim(s) 4 and 6 - 11 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1 is/are rejected.  
 7) Claim(s) 2,3 and 5 is/are objected to.  
 8) Claim(s) 1 - 11 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date 1/5/04 & 4/8/05.

4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

**Claims 1 – 11** are pending in the present application. Applicant's telephonic response to the restriction requirement has been entered (see below); accordingly, **Claim 4** and **Claims 6 – 11** were withdrawn from further consideration as being drawn to a non-elected invention pursuant to 37 C.F.R. §1.142(b). Therefore, **Claims 1 – 3** and **Claim 5** are currently pending in the application and were examined on the merits for patentability.

#### **Priority**

This application claims benefit of U.S. Provisional Application No. 60/472,572, filed May 22, 2003.

Acknowledgement is made of applicant's claim to foreign priority under 35 U.S.C. §§119(a) – (d), by German Patent Application No. 10300015.1, with filing date January 3, 2003.

#### **Information Disclosure Statement**

The Information Disclosure Statements filed on January 5, 2004 and April 8, 2005, are in compliance with 37 C.F.R. §1.97, and were considered by the examiner.

#### **Specification**

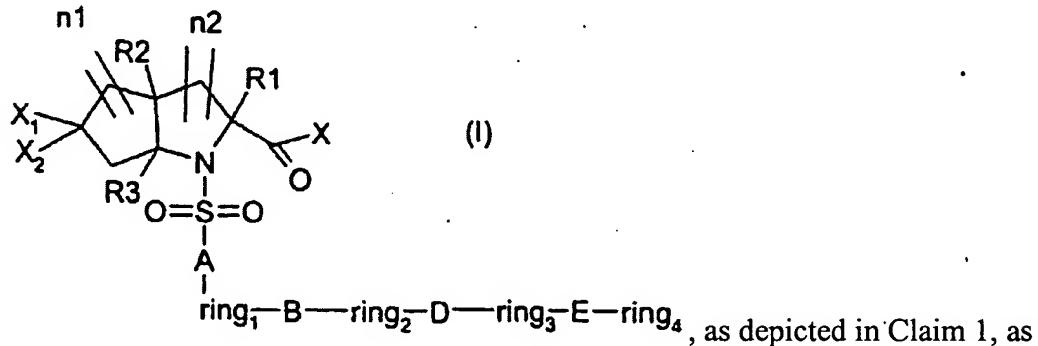
The Title in the first line of the Specification has a typographical error: "Derivative" should be "Derivatives."

#### **Election/Restrictions**

The Markush groups set forth in the claims include both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct

compounds, also far too numerous to list individually. **For these reasons provided below, restriction to one of the following inventions is required under 35 U.S.C. 121**, wherein an Invention is a set of patentably distinct inventions of a broad statutory category (e.g., compounds, methods of use, methods of making, etc.):

**I. Claims 1 – 3 and 5, drawn to compounds and compositions of formula (I)**



classified in Class 548, subclasses 181, 452, 454, 465; Class 544, subclasses 144 and 373; Class 546, subclass 114; and other subclasses.

**II. Claim 4, drawn to a process of preparing compounds of formula (I), as depicted in Claim 4, classified in Class 548, subclasses 181, 452, 454, 465; Class 544, subclasses 144 and 373; Class 546, subclass 114; and other subclasses.**

**III. Claims 6 – 11, drawn to methods of using compounds of formula (I), classified in Class 514, subclasses 235.2, 365, 412, 414, and other subclasses.**

**In addition to an election of one of the above Groups, restriction is further required under 35 U.S.C. §121 as follows:**

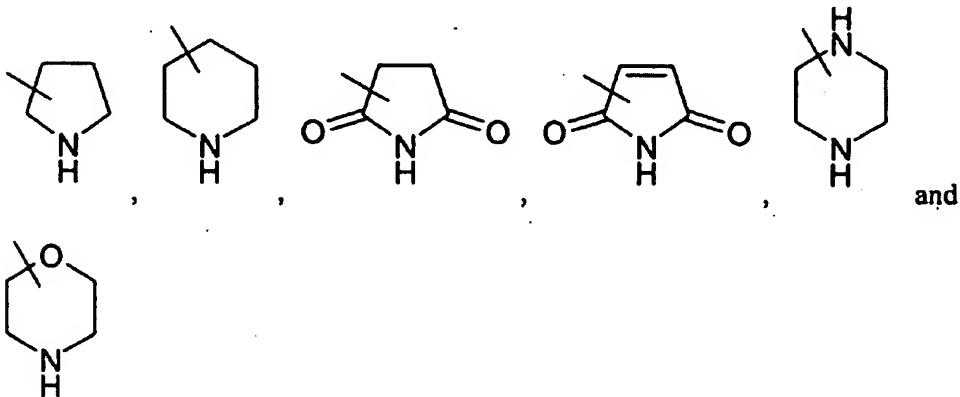
In accordance with the decisions in In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980) and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App & Int. 1984), restriction of a Markush group is proper where the compounds with the group either (1) do not share a common

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utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. §103 with respect to the other member(s).

Therefore, when one of **Groups I - III** is elected, **an election of a single compound of general formula (I) is further required**, including an exact definition of each substitution on the base molecule [i.e., general formula (I)], wherein a single member at each substituent group is selected. For example, if the base molecule of general formula (I) has substituent “**ring 4**” which is recited to be:

- $(C_6-C_{14})$ -aryl that is unsubstituted or substituted, independently of each other, once, twice or three times, by G,  
5- or 6-membered aromatic heteroaryl ring that is unsubstituted or substituted, independently of each other, once, twice or three times, by G,  
heteroaryl that is unsubstituted or substituted, independently of each other, once, twice or three times, by G, or  
azaheterocyclyl selected from the group consisting of



then applicant must select a single substituent representing “**ring 4**,” and its site of attachment, such as: “**ring 4** is a 4-morpholinyl group,” as well as specific values at each subsequent variable position (A, B, D, E, **ring 1**, **ring 2**, **ring 3**, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, X, X<sup>1</sup>, X<sup>2</sup>, n<sup>1</sup>, n<sup>2</sup>, o, n, m, G, p, q, r, R<sup>5</sup> and R<sup>6</sup>, if applicable), so that a single identifiable compound is selected.

One suggestion for the election of a compound would be to select one of the examples, Example 1 – Example 84, disclosed in the Specification at pp. 30 – 41.

Further, if **Group III** is elected, then **election of a specific method of use, along with an elected compound of general formula (I), is required**; for example, a method of treating:

- A. osteoarthroses;
- B. spondyloses;
- C. cartilage loss following joint trauma
- D. periodontal disease; etc.

using an “elected” compound of general formula (I).

In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim which fall into the same class and subclass as the elected compound, but may also include additional compounds which fall in related subclasses.

Examination will then proceed on the elected compound *and* the entire scope of the invention encompassing the elected compound as defined by common classification. A clear

statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits.

Note that the restriction requirement will not be made final until such time as Applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making the compounds under investigation. This will be set forth by reference to specific class(es) and subclass(es) examined.

Should Applicant traverse on the ground that the compounds are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

All compounds falling outside of the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to non-elected subject matter and will be withdrawn from consideration under 35 U.S.C. §121 and 37 C.F.R. §1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. §121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(i).

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can set forth a group of compounds which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP §608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

**Rationale Establishing Patentable Distinctiveness Within Each Group**

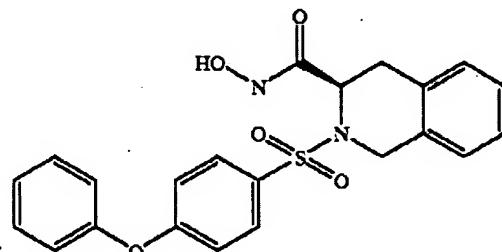
Each Group listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP §806.04, MPEP §808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group); i.e., they are patentable over each other. Chemical structures which are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

**The above Groups represent general areas wherein the inventions are independent and distinct, each from the other, because of the following reasons:**

**Group I and Group II** are related as products and a process of preparing the products.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the products as claimed can be made by another and materially different process. See MPEP § 806.05(f).

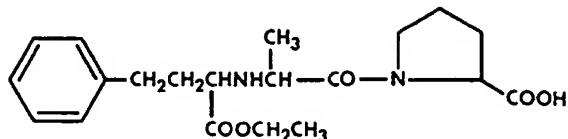
Applying this rule to the instant case, the process as claimed can also be used to make a materially-different product, R-2-(4-phenoxybenzenesulfonyl)-1,2,3,4-tetrahydroisoquinoline-3-



hydroxamic acid, which has the structure: See U.S.

**Patent 6,207,672 B1** (Thorwart, et al.)(cited on Applicant's Information Disclosure Statement, Form 1449) at col. 5, line 40 to col. 7, line 9; and at col. 12, line 1 to col. 13, line 12. **Group I** and **Group II** are therefore separate and distinct inventions for which restriction is appropriate.

**Group I and Group III** are related as products and methods of using the products. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially-different process of using that product. MPEP §806.05(h). Applying this rule to the instant case, the process for using the products as claimed – e.g., as treatment for heart failure (**Claim 10** at page 59, line 27) – may be practiced with a materially different product, such as the compound “enalapril,”



See Cohn, J. "The Management of Chronic Heart

Failure," N. Engl. J. Med., vol. 335(7), pages 490 – 498 (Aug. 1996), at p. 493, col. 2, line 47

(Table 2). **Group I** and **Group III** are therefore separate and distinct inventions for which restriction is appropriate.

**Group II** and **Group III** are related as a process of preparing and methods of using products of formula (I). The process of preparing and the method of using the compounds of formula (I) are classified separately in U.S. patent practice in Classes 544, 546, and 548 (process of preparing) and Class 514 (methods of using). The inventions of **Group II** and **Group III** have achieved separate status in the art and are separate and distinct inventions for which restriction is appropriate.

In addition, because of the multiple classes and subclasses within and across each of **Groups I-III**, and the divergent searches of the prior art that would be required for examination of all the inventions, a serious burden is imposed upon the examiner to perform a complete search of the defined areas. Therefore, for the reasons given above, the restriction set forth is proper, and not to restrict would impose a serious burden in the examination of this application.

#### Advisory of Rejoinder

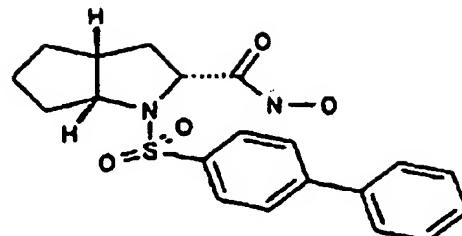
The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the**

**patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

**Election by Applicant by Telephone:**

During telephone conversations with **Joseph Rossi, Esq.**, on **July 6 and 7, 2005**, the above restriction requirements were discussed, and a provisional election was made by Applicant



of Group I and the chemical compound (Specification at

p. 38, line 6, "Example 64"). The election was made without traverse, but Applicant expressly reserved the right to rejoinder of process claims if the product claims were found to be allowable (see also "Advisory of Rejoinder" section, above).

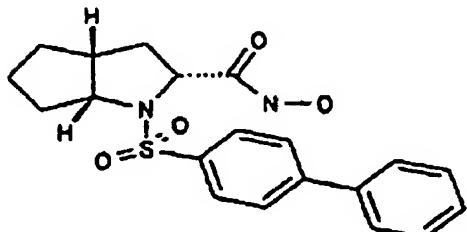
Applicant is advised that the reply to this requirement to be complete must include an election of the Invention to be examined even though the requirement be traversed. 37 C.F.R. §1.143.

Applicant is further advised that a reply to this requirement must identify the specific compound that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

**Prior Art Searched**

1) **Elected chemical compound**

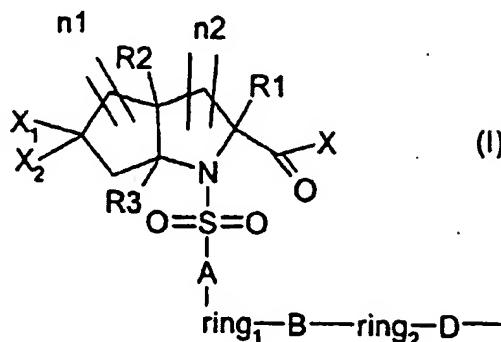
An initial search of the prior art was made for the chemical compound elected by Applicant in response to the restriction requirement (above),



(Specification at p. 38, line 6, "Example 64"). No prior art was found that anticipated or rendered obvious the elected compound.

2) Expansion of search of the art

The search of the prior art was expanded beyond the elected compound to encompass



those compounds of formula (I)  $\text{ring}_1\text{---B---ring}_2\text{---D---ring}_3\text{---E---ring}_4$ , in Class

548, subclasses 452 and 454; and in Class 514, subclasses 412 and 414, with the definitions of variables in formula (I) as depicted in Claim 1,

During the expanded search in the art defined above, the following prior art was found, as described in the rejections below.

Claim Rejections - 35 USC § 102(b)

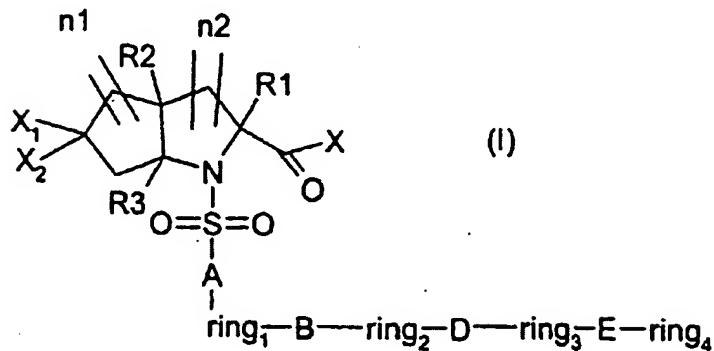
The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102(b) that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim 1** is rejected under 35 U.S.C. §102(b) as being anticipated by Nuhrich, A., and Moulines, J., "Cyclisation de N-Tosyl Oxiranes-Propylamines: Synthese D'Heterocycles Azotes," Tetrahedron, vol. 47(18/19), pages 3075-3088 (1991), at p. 3087, col. 1, lines 1 – 29 ("Examples 28A and 28 B") and lines 31 – 44 ("Example 29"). This reference was cited by Applicant on the Information Disclosure Statement (Form 1449).

Specifically, **Claim 1** of the present invention recites compounds of formula (I),



**n**<sup>1</sup> is  $-(CH_2)_r-$  and **r** is 1 (i.e., corresponding to a cyclopentane ring) [note: as described below in the section “Claim Objections,” the use of superscripts and subscripts for variables is inconsistent in the claims; all variables will be shown with superscripts here]; **n**<sup>2</sup> is  $-(CH_2)_q-$  and **q** is 1 (i.e., a pyrrolidine ring);

**X** is  $-OH$ ;

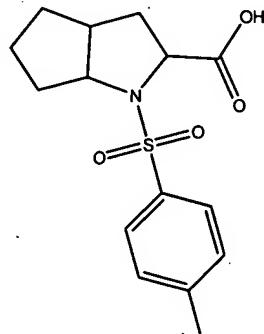
**ring**<sub>1</sub>, **ring**<sub>2</sub>, **ring**<sub>3</sub> are each a “covalent bond”;

**A**, **B**, **D** and **E** are each “ $-C_0$ ” [i.e., these variables drop out];

**ring**<sub>4</sub> is phenyl, substituted by **G** (which is **R**<sup>4</sup>, where **R**<sup>4</sup> is methyl); and

**X**<sup>1</sup>, **X**<sup>2</sup>, **R**<sup>1</sup>, **R**<sup>2</sup>, **R**<sup>3</sup> are each hydrogen,

then the genus structure of formula (I) is anticipated by the chemical compound



N-tosylperhydrocyclopenta[b]pyrrole-2-carboxylic acid, , disclosed in

Nuhrich, A., and Moulines, J., “Cyclisation de N-Tosyl Oxiranes-Propylamines: Synthese

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D'Heterocycles Azotes," Tetrahedron, vol. 47(18/19), pages 3075-3088 (1991), at p. 3087, col. 1, lines 1 – 29 ("Examples 28A and 28 B"), and lines 31 – 44 ("Example 29"). This chemical species directly anticipates the genus structure of formula (I) in **Claim 1** of the present invention; therefore, **Claim 1** is rejected under 35 U.S.C. §102(b) as anticipated by Nuhrich & Moulines.

**Claim Rejections - 35 USC § 102(e)**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102(e) that form the basis for the rejections under this section made in this Office action:

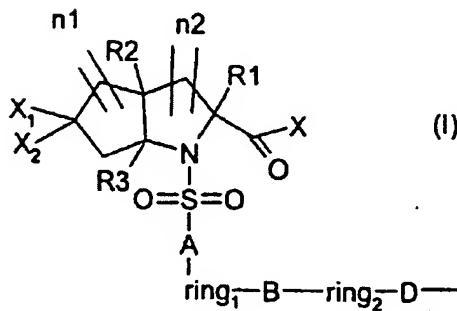
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claim 1** is also rejected under 35 U.S.C. §102(e)(2) as being anticipated by **U.S. Patent**

**No. 6,855,708 B2** (Lin, et al.)(filing date: March 13, 2002).

Specifically, **Claim 1** of the present invention recites compounds of formula (I),



ring<sub>1</sub>—B—ring<sub>2</sub>—D—ring<sub>3</sub>—E—ring<sub>4</sub>. In those instances where:

n<sup>1</sup> is -(CH<sub>2</sub>)<sub>r</sub>- and r is 2 (i.e., corresponding to a cyclohexane ring);

n<sup>2</sup> is -(CH<sub>2</sub>)<sub>q</sub>- and q is 1 (i.e., a pyrrolidine ring);

X is -OH;

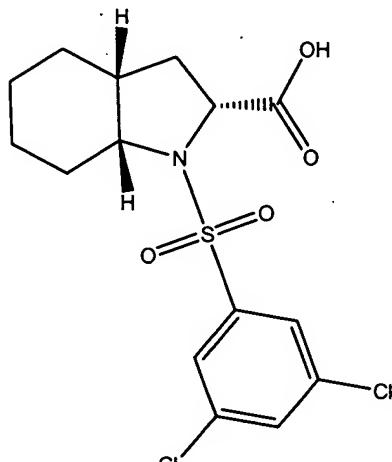
ring<sub>1</sub>, ring<sub>2</sub>, ring<sub>3</sub> are each a "covalent bond";

**A, B, D** and **E** are each  $C_0$  [i.e., these variables drop out];

ring<sub>4</sub> is phenyl, twice-substituted by **G**, where **G** is the halogen “Cl”; and

**X**<sup>1</sup>, **X**<sup>2</sup>, **R**<sup>1</sup>, **R**<sup>2</sup>, **R**<sup>3</sup> are each hydrogen;

then the genus structure of formula (I) is anticipated by the compound N-[3,5-dichlorobenzene)-sulfonyl]-(3a(S),7a(S))-octahydro-indole-2(S)-carboxylic acid, which has the structure:

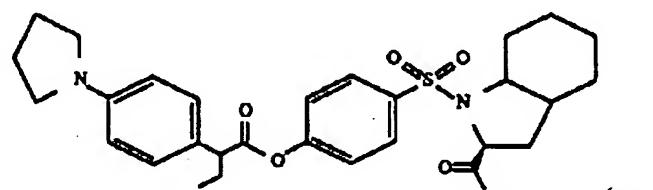


(see U.S. Patent No. 6,855,708 at col. 22, lines 46 – 56,

“Example 4-A”). This chemical species directly anticipates the genus structure of formula (I) in **Claim 1** of the present invention; therefore, **Claim 1** is rejected under 35 U.S.C. §102(e)(2), as anticipated by U.S. Patent No. 6,855,708.

#### Analysis of Closest Prior Art for Claims 2 and 3

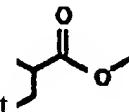
**Claims 2 and 3**, which depend from **Claim 1**, appear to be free of the art of record. For **Claims 2 and 3**, the closest art of record appears to be in U.S. Patent No. 5,795,890 (Nakae, et al.), which discloses the compound 4-(2S-carboxyhydroindol-1-ylsulfonyl)phenyl-2RS-(4-



(pyrrolidine-1-yl)phenyl)butanoic acid ester,

(see

U.S. Patent No. 5,795,890, at col. 288, lines 43 – 44, claim 7; and col. 164, lines 1 – 21, “Example 2(34)”). This compound would meet all of the limitations of **Claims 2 and 3**, except

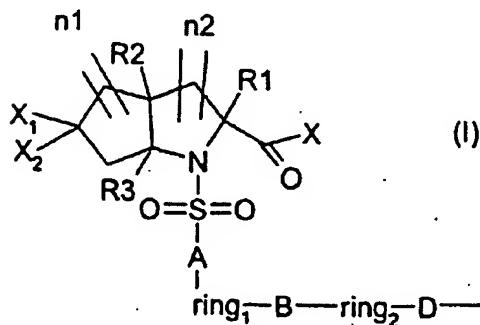


that the limitations of variables **B**, **D** and **E** in formula (I) do *not* permit (butanoic acid) as one of the linking groups.

### Claim Objections

**Claims 2, 3 and 5** are objected to as being dependent upon a rejected base claim, but appear to be free of the art if rewritten in independent form including all of the limitations of the base claim and any intervening claims. See MPEP §608.01(n)(V).

**Claim 1** is objected to because the drawing of the structure of formula (I),



has several features which render the claim unclear and ambiguous in meaning. According to the definition provided in the Specification, the two parallel lines leading to “n1” and “n2” in the drawing above mean “ $-(CH_2)_q-$ ” and “ $-(CH_2)_r-$ ,” respectively, where q and r are each “zero, 1, 2 or 3,” and “where the variables n<sup>1</sup> or n<sup>2</sup> indicate the number of the -CH<sub>2</sub>- radicals in the ring of formula (I).” (Specification at p. 8, lines 13 – 24). Although the Specification’s description is helpful, the use of two parallel lines leading to a single variable is ambiguous, and should be clarified.

**Claim 1** is also objected to because it ends with two periods.

In addition, **Claim 1** is objected to because of inconsistent use of superscripts and subscripts for several variables in formula (I) and the corresponding definitions. For example, formula (I) shows the variables “ $X_1$ ” and “ $X_2$ ” in the structure drawn on page 44, but the definitions of these variables use “ $X^1$ ” and “ $X^2$ .” (Specification at p. 46, line 18). Likewise, variables  $n_1$ ,  $n_2$ ,  $R_1$ ,  $R_3$ ,  $ring_1$ ,  $ring_2$ ,  $ring_3$  and  $ring_4$  in the structure of formula (I) on p. 44 are defined later as  $n^1$ ,  $n^2$ ,  $R^1$ ,  $R^3$ ,  $ring\ 1$ ,  $ring\ 2$ ,  $ring\ 3$  and  $ring\ 4$  on pp. 45 and 46 of the claims.

**Claim 2 and Claim 3** are objected to for the following misspellings:

“as” [for “is” or “are”] (at p. 47, line 32; p. 48, line 13; p. 49, line 15; p. 52, line 14; p. 53, line 31; and p. 55, lines 1, 9 and 25);

“fuaranyl” (at p. 48, line 30; p. 49, line 22; p. 50, line 12; p. 51, lines 4 and 29; p. 52, line 21; p. 53, line 11; and p. 54, line 3);

“puryanyl” (at p. 49, lines 2 and 29; p. 50, line 19; p. 51, line 11; p. 52, lines 1 and 28; p. 53, line 18; and p. 54, line 10); and

“pryidooxazolyl” (at p. 49, lines 3 and 30; p. 50, line 20; p. 51, line 12; p. 52, lines 2 and 29; p. 53, line 19; and p. 54, line 11).

**Claim 4**, although not examined in this action for prior art as drawn to a non-elected claim, has the following claim objections, for the information of the applicant:

On page 57, line 16, the claim appears to be missing a verb, such as “reacting.”

On page 59, line 3, step (d), it is not clear to which noun the term “it” refers.

On page 57, line 24, the variables “ $ring^1$ ,  $ring^2$ ,  $ring^3$ , and  $ring^4$ ” refer to their definitions in formula (I) in **Claim 1**, but are “ $ring_1$ ,  $ring_2$ ,  $ring_3$  and  $ring_4$ ” in the structure of formula (I) on p. 44, and by “ $ring\ 1$ ,  $ring\ 2$ ,  $ring\ 3$  and  $ring\ 4$ ” on p. 45, lines 6 and 12.

**Conclusion**

**Claim 1** is rejected under 35 U.S.C. §102(b) and under 35 U.S.C. §102(e)(2).

**Claims 2, 3 and 5** are objected to as dependent upon a rejected base claim.

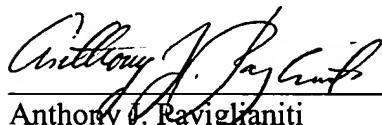
**Claims 1, 2 and 3** are also objected to for the reasons described above.

**Claim 4** and **Claims 6 – 11** were withdrawn as being drawn to a non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Anthony J. Paviglianiti** whose telephone number is (571) 272-3107. The examiner can normally be reached on Monday-Friday, 8:30 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph K. McKane**, can be reached at (571) 272-0699. **The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.** Please note that this is a new central FAX number for all official correspondence.

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